

Existing Research Specimens

38CFR16.101(b) (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

1. According to the Office for Human Research Protections (OHRP), "to qualify for this exemption criteria the data, documents, records, or specimens must be in existence at the time of IRB review. The principle behind this policy is that the rights of individuals should be respected; subjects must consent to participation in research."
2. OHRP interprets the term "existing" to mean that all of the data, documents, records, or specimens to be used in the research are in existence prior to IRB review and were collected for purposes other than the proposed research. The Reviewer must assure that the investigator has shown that all of data to be collected under this category are currently in existence at the time of IRB review.
3. Based on the federal definition of "existing data," research conducted on biological or pathologic specimens obtained prospectively and taken strictly for *research purposes* does not qualify for exempt review. Not only do these samples not meet the definition of "existing" but these samples would not be "publicly available."
4. Based on the federal definition of "existing data," research conducted on biological or pathologic specimens obtained prospectively from future *discarded clinical samples* does not qualify for exempt review. Even though the samples would be obtained for clinical purposes and would be discarded, because it is a prospective study, it does meet the definition of "existing" and, therefore, requires full review.
5. If the biological or pathological samples are being obtained by means of retrospective collection from existing sources, there is a very narrow window in which the use of these samples for research purposes will qualify for exempt review (**Appendix DD**). However, if the samples are given to the investigator with any hospital numbers, codes or links that tie the data back to a list of subjects, and there is a mechanism by which the subject can be identified, directly or indirectly, the research does not qualify for exempt review.
6. If the PI receives the samples and these samples are truly anonymous, and no one can link a specific sample with a specific subject, the study likely is research not involving human subjects and will require a conversation with the IRB Chair. The IRB Chair may make a determination that it is not human subject research or refer to the IRB as needed. This research still requires R&D Committee approval.
7. Due to advances in science, the IRB has adopted a policy on informed consent when the research involves genetic testing or tissue/DNA banking. If the samples/specimens are being collected for these purposes, full review will be required. A second consent form is required when genetic research is requested in addition to a therapeutic study. The Reviewer should consult the IRB policy.
8. If the collection of the data will be from documents or records that are in existence at the time of IRB review and there is absolutely no identifiable information recorded by the investigator (even if there is identifiable information provided to the investigator), the procedures will qualify for exempt review. However, if the information is not publicly available and the investigator needs to cross reference the data collected with other records, this will not meet the criteria for exemption and will need either full or expedited review. Also, if there is any prospective component of the research procedures, for example information taken from existing records which will be compared to information to be collected at some future date, the research will not qualify for exempt review.